

Remarks and Arguments:

Claims 54-63 are currently pending in this application. Claims 1-53 have been cancelled.

Claims 54-63 stand rejected under 35 U.S.C. § 102(e) as anticipated by Gresser et al.

Claim 54 calls for a drug delivery system having, among other things, a flexible pad containing a plurality of release pads with each release pad containing an electroactive polymer and medication. Contact points are operatively connected to the release pads such that an instruction station may selectively initiate a release of the medication from the electroactive polymer in a desired release pad by sending a signal to a contact point, which then delivers electrical potential to a release pad. Claims 55-60 depend from Claim 54. The structure of Claim 54 allows a high degree of control over timing and dispensing of a target medication. Because of this selective release capability, the medication is immediately available, at a pre-set time or whenever deemed appropriate by the user, for introduction into a patient. Claim 61 calls for a method of medicating a patient utilizing the structure taught in Claim 54. Claims 62-63 depend from Claim 61.

Gresser discloses an implantable drug delivery device consisting of a series of polymeric “bursting” units that react to the implanted environment and dispense a drug upon bursting. Gresser operates largely on osmotic pressure, without use of electricity. The control allowed in the system disclosed by Gresser relies upon the use of “bursting” units of different sizes and thicknesses that, once implanted in a patient, cannot be controlled without removal. The structure of Claim 54 allows an individual to initiate a release just minutes after attaching the system to a patient or days later, as the situation demands. Gresser fails to disclose a structure similar to Claim 54. Since Claim 61 teaches a method of medicating a patient utilizing a system according to Claim 54 and Gresser does not disclose a similar system, Gresser also does not

disclose a method according to Claim 61. Thus, Gresser cannot anticipate the instant application and Applicant respectfully requests that the Examiner withdraw the rejection.

Claims 54-63 stand rejected under 35 U.S.C. § 102(e) as anticipated by Pickett et al. Again, Claim 54 calls for a drug delivery system having, among other things, a flexible pad containing a plurality of release pads with each release pad containing an electroactive polymer and medication. Contact points are operatively connected to the release pads such that an instruction station may selectively initiate a release of the medication from the electroactive polymer in a desired release pad by sending a signal to a contact point, which then delivers electrical potential to a release pad. Claims 55-60 depend from Claim 54. The structure of Claim 54 allows a high degree of control over timing and dispensing of a target medication. Because of this selective release capability, the medication is immediately available, at a pre-set time or whenever deemed appropriate by the user, for introduction into a patient. Claim 61 calls for a method of medicating a patient utilizing the structure taught in Claim 54. Claims 62-63 depend from Claim 61.

Pickett discloses a multi-layer electroactive polymer electrode, each layer of which may be impregnated with a target ionic drug for delivery. This multi-layer provides a variety of functions including allowing the surface to be aqueous wettable or to provide bio-compatibility. Example three discloses a multi-layer electrode with each layer having a different "electro-release system". *See*, Pickett et al., col 4:66-col 5:6. However, the multi-layer electrode disclosed by Pickett does not afford the same degree of control allowed by an electrode according to the instant invention. A stimulating charge provided to the electrode disclosed by Pickett would necessarily trigger a delivery of a mixture of all the ionic drugs loaded on that electrode. Pickett does not disclose a means to selectively control the release of each of these

layers independently as taught in the instant application. The plurality of independently addressable pads on a single unit taught by Claim 54 allows a remote instruction station to trigger a single release of a desired drug without triggering release of any of the other drugs loaded on the electrode if so desired. Thus, the structure disclosed in Pickett does not fully anticipate Claim 54 of the instant application. Since Claim 61 teaches a method of medicating a patient utilizing a system according to Claim 54 and Pickett does not disclose a similar system, Pickett also does not disclose a method according to Claim 61.

Moreover, the inner polymer layer of Pickett provides release by generating protons electrochemically which disturb the active molecule's binding to the polymer, allowing a release. This mechanism, however, will allow only a release that is Faradaic in nature because each proton generated will only be able to work upon a single active molecule site. Pickett is therefore restricted to a purely Faradaic delivery of medication while the instant application is capable of both Faradaic and non-Faradaic ("burst") release. Thus, Pickett cannot fully anticipate the instant application, either Claims 54 or 61, and Applicant respectfully requests that the Examiner withdraw the rejection.

Claims 54-63 stand rejected under rejected under 35 U.S.C. § 103(a) as rendered obvious by Miller et al. Again, Claim 54 calls for a drug delivery system having, among other things, a flexible pad containing a plurality of release pads with each release pad containing an electroactive polymer and medication. Contact points are operatively connected to the release pads such that an instruction station may selectively initiate a release of the medication from the electroactive polymer in a desired release pad by sending a signal to a contact point, which then delivers electrical potential to a release pad. Claims 55-60 depend from Claim 54. The structure of Claim 54 allows a high degree of control over timing and dispensing of a target medication.

Because of this selective release capability, the medication is immediately available, at a pre-set time or whenever deemed appropriate by the user, for introduction into a patient. Claim 61 calls for a method of medicating a patient utilizing the structure taught in Claim 54. Claims 62-63 depend from Claim 61.

Miller discloses a single reloadable electroactive polymer electrode capable of drug delivery. The Office contends that the use of multiple electrodes within a single unit would be an obvious matter of design. The inclusion of a plurality of independently addressable release pads within a single controlled unit is not a simple matter of design duplication of Miller. To establish a prima facie case of obviousness, there must be 1) a suggestion to combine or modify, 2) a reasonable expectation of success and 3) the references must suggest all of the claim limitations. MPEP § 2143. While the Office may rely on rationale from common knowledge in the art or scientific principles, the mere argument that the claimed invention is within the capability of one of ordinary skill in the art is not sufficient to establish prima facie obviousness. See MPEP § 2143.01; 2144. The structure of Claim 54 allows a great deal of flexibility in administration of medication. Releases from the plurality of release pads may be individual, a staggered release of multiple pads, or a simultaneous release of all the pads. This structure is not disclosed in Miller. A mere duplication of Miller would not allow simultaneous release of all of the pads, nor a staggered or timed release. Thus Claim 54 is not merely a matter of design over Miller, nor does Miller render the instant application obvious. Since Claim 61 teaches a method of medicating a patient utilizing a system according to Claim 54 and Miller does not disclose a similar system, Miller also does not disclose a method according to Claim 61. The Office has not provided any further basis to render the instant application obvious in view of Miller.

Applicant, therefore, respectfully requests that the Examiner withdraw the pending 35 U.S.C. § 103(a) rejection based upon Miller.

Claims 1-53 stand provisionally rejected under an obviousness-type double patenting rejection as unpatentable over claims 1-53 of the co-pending Application No. 09/929,197. In order to provide a complete response, Applicant presumes that the provisional double patenting rejection is in relation to the currently pending claims 54-63 rather than claims 1-53, which were cancelled by Applicant in Amendment A. Applicant's remarks are therefore in response to a provisional double patenting rejection over the currently pending claims 54-63. Due to the uncertainty surrounding this rejection on formerly cancelled matter, Applicant respectfully requests that the Office withdraw the finality of this Office Action.

An obviousness-type double patenting is only proper where a second patent's claims are not patentably distinct from the first patent or application. *In re Leonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). Claims 54 and 61 are patentably distinct over the cited co-pending application. Claim 54 is directed towards a pad having a plurality of release pads, each capable of electrochemically releasing a selected medication upon command. This allows a great deal of flexibility in treatment. Releases from the plurality of release pads may be individually triggered, a staggered release of multiple pads, or a simultaneous release of all the pads. Claims 55-60 depend from Claim 54. Claim 61 teaches a method of medicating a patient utilizing the structure of Claim 54. Claims 62-63 depend from Claim 61.

Co-pending Application No. 09/929,197 is an application drawn to electrodes exhibiting a novel burst release and methods for preparing same and the use of these electrodes in treatment. Only Claims 58-60 of the pending application incorporate a novel burst release, but do so in a different structure. Claim 54, from which Claims 58-60 depend, allows selective

release of a medication from a desired release pad or any configuration of release pads, a capability not taught or suggested in the co-pending application. The structure of Claim 54 is not claimed or disclosed in the co-pending application, nor does the co-pending application render Claim 54 of the instant invention obvious. Therefore, the instant application, is patentably distinct from the co-pending application. Applicant, therefore, respectfully requests that the provisional double patenting rejection based upon pending Application No. 09/929,197 be withdrawn.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone the undersigned at the number provided.

This amendment should now be entered into the record. The number of issues have been reduced and clarified. There are no new issues that would require further consideration and/or search. All rejections are overcome and should be withdrawn. The application and all claims therein are placed in better condition for allowance or alternatively for appeal by materially reducing, eliminating and/or simplifying the issues for any such appeal by this amendment. Allowance of all claims and passing to issue is requested.

Prompt and favorable consideration of this Amendment is respectfully requested.

Respectfully submitted,



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